IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: SUBOXONE (BUPRENORPHINE HYDROCHLORIDE AND NALOXONE) ANTITRUST LITIGATION	:	**MDL NO. 2445 13-MD-2445**
THIS DOCUMENT APPLIES TO: ALL ACTIONS	:	

Goldberg, J. **June 27, 2016**

MEMORANDUM OPINION

This multi-district litigation case involves a relatively new theory of alleged antitrust liability, which is premised on the unique regulatory and statutory scheme that governs the marketing and distribution of pharmaceutical drugs. Under this theory, commonly referred to as "product hopping," a pharmaceutical company makes modest reformulations to a brand name drug prior to the expiration of its market exclusivity for the purpose of stymieing generic competition and preserving monopoly profits.

Here, Plaintiffs, the Direct Purchasers of Suboxone ("Direct Purchasers") and the End Payors of Suboxone ("End Payors") claim that Defendant Indivior, Inc.[1] switched from sublingual Suboxone tablets to a sublingual Suboxone film for the purpose of foreclosing generic competition. This switch, the "product hop," was allegedly accompanied by Indivior disparaging the tablet through fabricated safety concerns and ultimately removing Suboxone tablets from the market just as generic Suboxone tablets were able to begin competing. Indivior is also alleged to have manipulated FDA regulations to delay the entry of generic Suboxone onto the market, thereby unlawfully maintaining a monopoly in violation of Section 2 of the Sherman Act.

[1] Indivior was formerly known as Reckitt Benckiser.

According to Plaintiffs, Indivior's conduct foreclosed competition and resulted in ongoing overpayments.

On December 23, 2015, I referred resolution of all non-dispositive discovery disputes to Magistrate Judge Timothy R. Rice. Presently before me are Indivior's objections to Magistrate Judge Rice's Order denying its motion to compel Direct Purchasers to produce "downstream" discovery. Indivior presses that downstream sales transactions undertaken by a direct purchaser of pharmaceutical drugs are relevant to issues of antitrust liability and, thus, are discoverable. For the reasons that follow, Indivior will be permitted to pursue discovery of this information.

I. FACTUAL AND PROCEDURAL BACKGROUND

a. Pertinent Portions of the Motion to Dismiss Ruling

A brief review of my December 3, 2014 opinion regarding Indivior's motion to dismiss is necessary to place the issue currently before me into context. See In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., 64 F. Supp. 3d 665 (E.D. Pa. 2014). In that opinion, regarding the "product-hop" claim, I determined that Direct Purchasers had plausibly pleaded exclusionary conduct, finding that:

> the facts presented sufficiently allege that the disparagement of Suboxone tablets took place alongside 'coercive' measures. The threatened removal of the tablets from the market in conjunction with the alleged fabricated safety concerns could plausibly coerce patients and doctors to switch from tablet to film. A patient that preferred the tablets despite the safety concerns might be further persuaded to switch to the film, believing that their favored product would soon be removed from the market.

Id. at 682.

I further concluded that "Plaintiffs have plausibly alleged that various market forces unique to the pharmaceutical industry make generic substitution the cost-efficient means of competing for companies selling generic pharmaceuticals." Id. at 683-84. In so holding, I noted

that "Plaintiffs assert that a disconnect exists between the person paying for the prescription and the person selecting the appropriate treatment, [and] due to this disconnect, the ordinary market forces that would allow consumers to consider price when selecting a production are derailed." Id. at 684. Direct Purchasers refer to this phenomenon as a "price disconnect."

b. The Dispute Regarding Downstream Discovery

On July 17, 2015, Indivior propounded document requests and interrogatories requesting, among other things, information relating to Direct Purchasers' sales and to the pricing structures encountered by other downstream market participants. Indivior's "discovery requests call for the production of data and documents showing the prices that have been charged, the rebates and discounts offered by the competing manufacturers, the impact that pricing decisions have on market share and volume, and related topics." (Def.'s Mot. to Compel p. 4.) Direct Purchasers objected to this discovery on the ground that any pricing information beyond their own purchases was irrelevant as a matter of law.

On January 4, 2016, Indivior filed a motion to compel Direct Purchasers to produce this downstream discovery. Following a telephone conference, Judge Rice issued an Order dated January 14, 2016 directing Indivior to submit an expert declaration "explaining why the discovery of 'downstream information' is relevant." Judge Rice also directed Direct Purchasers to respond to the motion to compel by February 10, 2016 and stated that any reply from Indivior was to be filed by February 17, 2016. On January 27, 2016, Indivior submitted a declaration from an economist, Dr. Parker Normann.[2] Direct Purchasers filed their response on February 10, 2016.

[2] Dr. Normann has provided "analysis, reports, or testimony for dozens of antitrust litigation cases, mergers, or regulatory matters, including testifying in or providing consulting for the pharmaceutical cases." (Def.'s Objs., Ex. A ¶¶ 1-2.)

c. Judge Rice's Order and Analysis

On February 16, 2016, Judge Rice denied Indivior's motion to compel the requested discovery. Therein he stated that "[t]he downstream price charged throughout the chain of distribution is irrelevant to plaintiffs' alleged damage for overcharges. The relevant inquiry is whether, in the unique market . . . defendant's alleged 'product hopping' caused plaintiffs to pay more than they would have paid absent any unlawful conduct to suppress competition." (Or. p. 2, Feb. 16, 2016.)

Judge Rice reasoned that "[p]laintiffs must prove that defendant's conduct caused plaintiffs to be unlawfully overcharged in the first instance; whether plaintiffs or others subsequently passed on, or discounted, the overcharges to customers has no bearing on any threshold antitrust violation." (Id.) He further explained that "[n]o legal authority supports defendant's request. See Hanover Shoe, Inc. v. United Shoe Machinery Corp., 392 U.S. 481, 490-94 (1968) (barring evidence of charges that were passed on or passed through); Activas [sic] PLC, 787 F.3d at 655-56; In re Niaspan Antitrust Litig., 2015 WL 4197590 (E.D. Pa. July 9, 2015) (collecting cases)." (Or. p. 3, Feb. 16, 2016.)

Additionally, Judge Rice stated that "[a]lthough defendant maintains that the absence of downstream evidence will impair plaintiffs' ability to prove an antitrust injury, . . . that concern will be resolved at a later date by Judge Goldberg." (Id.)

Lastly, Judge Rice found that "[e]ven assuming the relevance of the evidence defendant demands, the request violates the proportionality test of Fed. R. Civ. P. 26." (Id.) Judge Rice reasoned that "Dr. Normann's [Indivior's expert] justification for the evidence is equivocal . . . whereas the burden on plaintiffs, who hold a modest market share of Suboxone . . . would be significant." (Id.)

II. STANDARD OF REVIEW

a. Standards for Reviewing the Objections to Judge Rice's Order

When a pretrial matter not dispositive of a party's claim or defense is referred to a magistrate judge, "the magistrate judge must promptly conduct the required proceedings and, when appropriate, issue a written order stating the decision. A party may serve and file objections to the order within 14 days after being served with a copy." Fed. R. Civ. P. 72(a). "The district judge in the case must consider timely objections and modify or set aside any part of the order that is clearly erroneous or is contrary to law." Id.

The parties disagree as to how the foregoing standard of review should be applied to Judge Rice's Order denying Indivior's motion to compel. Direct Purchasers urge that a "magistrate judge's determination of the relevancy of documents sought in discovery, and the associated burden of production, is reviewed for an abuse of discretion." (DPPs' Resp. p. 5.) Indivior urges that I should apply a de novo standard.

Issues of relevancy "are traditionally left to the discretion of the trial court," and, consequently, "the standard of review in most instances is not the explicit statutory standard, but the clearly implicit standard of abuse of discretion." Conway v. State Farm Fire & Cas. Co., 1998 WL 961365, at *1 (E.D. Pa. Dec. 11, 1998); see also, Scott Paper Co. v. United States, 943 F. Supp. 501, 502 (E.D. Pa. 1996) ("The Court may overrule a decision of the Magistrate Judge involving a nondispositive discovery dispute only if the decision is clearly erroneous or contrary to law, or if the Magistrate Judge abused his discretion"); Skoora v. Kean Univ., 2013 WL 6094446, at *2 (D.N.J. Nov. 15, 2013) ("Where a Magistrate Judge is authorized to exercise his or her discretion, as in a discovery matter . . ., the District Court will reverse the decision only for an abuse of that discretion"); Saldi v. Paul Revere Life Ins. Co., 224 F.R.D. 169, 174 (E.D. Pa.

2004) ("When a magistrate judge's decision is on a highly discretionary matter, courts in this district have determined that the clearly erroneous standard implicitly becomes an abuse of discretion standard").

I will, therefore, apply the abuse of discretion standard.

b. Discovery Standards

The Federal Rules of Civil Procedure define the scope of permissible discovery as follows:

> Unless otherwise limited by court order, the scope of discovery is as follows: Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.

Fed. R. Civ. P. 26(b)(1). Evidence is relevant if "it has any tendency to make a fact more or less probable than it would be without the evidence" and "the fact is of consequence in determining the action." Fed. R. Evid. 401.

III. DISCUSSION

a. The Parties' Positions – Relevance of the Requested Discovery

Indivior primarily contends that the downstream evidence it seeks is relevant to issues of liability under Direct Purchasers' product hop theory.[3] As noted above, Direct Purchasers' product hop theory relies on the allegation that a disconnect exists between patients and insurers who pay for a drug and doctors who make the decision as to which drug to prescribe. Direct

[3] Indivior also argues that downstream data is relevant to certification of the putative Direct Purchaser class, End Payors' damages and the definition of the relevant market. As I have concluded that downstream data may be relevant to issues of liability, I need not reach these other arguments.

Purchasers allege that this "price disconnect" derails ordinary market forces that allow consumers to consider price when selecting a product. Direct Purchasers explain that, as a result of this price disconnect, the automatic generic substitution system is the only cost-efficient means of generic competition, and that manipulation of this system is what gives rise to antitrust liability.

Given that these allegations are central to the product hop claim, Indivior responds that Direct Purchasers must offer evidence at trial to prove that the "price disconnect" actually exists and that the generic substitution system is in fact the only cost-efficient means of generic competition.

Indivior asserts that it is not established, as a matter of law in all cases, that the only cost-efficient method of generic competition in the pharmaceutical industry is the automatic generic substitution system. Indivior urges that the viability of competition by other means is a factual issue to be resolved on the basis of the record in each case. Indivior thus presses that Direct Purchasers must offer evidence to establish that they were excluded from all cost-efficient means of distribution not just the regulatory mechanism they preferred.

According to Indivior, whether pricing, advertising or other strategies are cost-efficient means of generic competition remains an open factual question and that discovery on downstream data is necessary to determine whether viable alternatives outside of the automatic generic substitution system were available to Direct Purchasers. Indivior points out that some evidence already produced during discovery suggests that there was in fact vigorous competition even after the exclusionary conduct is alleged to have occurred. Because "price disconnect" is an essential element of Direct Purchasers' theory of liability, Indivior urges that Judge Rice erred in failing to allow the requested discovery.

Regarding relevant precedent, Indivior points out that product hop claims are novel and that a growing number of cases have recognized the relevance of downstream sales practices. For example, Indivior cites to Mylan Pharmaceuticals, Inc. v. Warner Chilcott Public Company, 2015 WL 1736957 (E.D. Pa. Apr. 16, 2015) ("Doryx") where the Honorable Paul S. Diamond of this court granted summary judgment in favor of the defendants on a product hop claim, finding that:

> there was no exclusionary conduct. [Plaintiff] Mylan remains able to reach consumers through, inter alia, advertising, promotion, cost competition, or superior product development. Mylan instead seeks to take advantage of generic substitution laws and thus increase its profits. Defendants have no duty to facilitate Mylan's business plan by keeping older versions of branded Doryx on the market. Defendants certainly did not exclude competition by denying Mylan the opportunity to take advantage of a regulatory 'bonus.'

Id. at *14.

Indivior has also submitted the affidavit of Dr. Normann to demonstrate how it could use the sought after information to disprove Direct Purchasers' price disconnect theory and demonstrate that other cost-efficient means of competition, such as pricing, were available to Direct Purchasers.[4] Dr. Normann further opined that, to evaluate Direct Purchasers' allegations of coercion, one needs to understand "the actual sales at the point at which the alleged coercion took place (that is, the point at which doctors and patients made the decision to choose brand

[4] In setting forth how an economist could use downstream data to test Plaintiff's allegations, Dr. Normann explains that evidence of the price charged by Direct Purchasers "relative to their acquisition costs . . . is needed to assess whether . . . any of the alleged price increase to force switching from brand tablets to brand film was actually passed through to those that determine demand." (Def.'s Obj., Ex. A p. 5.) To the extent that Indivior intends to use downstream data in this manner, such use would be clearly prohibited by Hanover Shoe. See 392 U.S. at 494.

Outside of the references to a pass through analysis, Dr. Normann sets out an adequate explanation as to how this data might be used to test Direct Purchasers' product hop theory of liability.

film over tablets)." (Def.'s Objs. Ex. A. ¶9.) Dr. Normann purports to offer eight "types of analyses that could be supported by plaintiffs' data." (Id. at ¶12.)

Direct Purchasers respond that Congress "conclusively established" that the automatic generic substitution system is the sole cost-efficient method of generic competition when it passed the Hatch-Waxman Act[5] and that various states concurred when they passed automatic generic substitution laws. (DPPs' Resp. p. 10.) As such, Direct Purchasers urge that Indivior may not challenge that legislative determination by attempting to demonstrate that other avenues of competition were available. Direct Purchasers object that Indivior is trying to "reopen a legal issue that is now closed by this Court, by Hatch-Waxman and the state legislatures." (Id. at 11.)

Direct Purchasers urge that the Doryx court erred when it concluded that the automatic generic substitution laws were a regulatory "bonus." According to Direct Purchasers, Doryx is an outlier and other courts have concluded that the automatic generic substitution system is the sole cost-efficient means of generic competition. In support, Direct Purchasers cite to New York v. Actavis, 787 F.3d 638 (2nd Cir. 2015) (Namenda II), a recent opinion in a product hop case, which states:

> Defendants and their amici argue that generics can successfully compete by persuading third-party payors and prescription-benefit managers to promote generic [drugs] through the use of formularies, tiered-drug structures, step programs, and prior-authorization requirements. But, as the district court determined, competition through state drug substitution laws is the only cost-efficient means of competing available to generic manufacturers. . . . For there to be an antitrust violation, generics need not be barred "from all means of distribution" if they are "bar[red] ... from the cost-efficient ones." Microsoft, 253 F.3d at 64; see also United States v. Dentsply Int'l, Inc., 399 F.3d 181, 191 (3d Cir.2005) ("The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit.").

Namenda II, 787 F.3d at 655-56.

[5] The relevant provisions of the Hatch-Waxman Act and the automatic generic substitution system it established are set forth in the motion to dismiss ruling. See In re Suboxone, 64 F. Supp. 3d at 673.

Direct Purchasers further cite to Abbott Laboratories v. Teva Pharmaceuticals USA, Inc., 432 F. Supp. 2d 408 (D. Del. 2006) ("TriCor"), another product hop case, which they contend held that the "automatic substitution system is not some 'bonus,' it is the structure that the legislatures created specifically to be the cost-efficient means of price competition." (DPPs' Resp. p. 12 (citing TriCor, 432 F. Supp. 2d at 423.)

In further support of their position, Direct Purchasers urge that the discovery Indivior seeks runs afoul of the Supreme Court's holding in Hanover Shoe because "damages in a direct purchaser antitrust suit are measured by the overcharge." (DPPs' Resp. p. 8.) According to Direct Purchasers, Indivior's argument that the generic companies should have promoted their products to doctors and insurers is an attempt to distract from this "consistent caselaw." (Id.)

Direct Purchasers point out that courts have also repeatedly denied defense requests for downstream discovery in pharmaceutical cases as contrary to the United States Supreme Court's holding in Hanover Shoe and Illinois Brick Co. v. Illinois, 431 U.S. 720, 745-46 (1977). See e.g., In re Niaspan Antitrust Litig., 2015 WL 4197590, at *1 (E.D. Pa. July 9, 2015) (denying request for downstream discovery as irrelevant to question of damages under Hanover Shoe); Braintree Labs., Inc. v. McKesson Corp., 2011 WL 5025096, at *1 (N.D. Cal. Oct. 20, 2011) (evidence of generic bypass is "irrelevant to whether class members have suffered any antitrust injury at all, and therefore is relevant to the commonality class certification inquiry")

Lastly, even if permissible as a matter of law, Direct Purchasers urge that Indivior has failed to explain how the downstream discovery is relevant to liability in this particular case. Direct Purchasers assert that Judge Rice correctly rejected Dr. Normann's explanation regarding how this evidence could be used as "equivocal."

b. Analysis

Judge Rice's determination that downstream evidence is irrelevant to Direct Purchasers' damages was not an abuse of discretion nor contrary to the law. See Hanover Shoe, 392 U.S. at 494. However, for the reasons that follow, I conclude that the downstream evidence Indivior seeks is potentially relevant to issues of liability under a product hop theory. As such, I will overrule Judge Rice's Order denying Indivior's motion to compel and allow Indivior to pursue downstream discovery.

Indivior correctly points out that, in opposing the motion to dismiss, Direct Purchasers emphasized the supposed price disconnect in the pharmaceutical industry and the allegation that purchases of Suboxone were coerced. I specifically relied on these allegations when I found that Direct Purchasers had plausibly alleged exclusionary conduct. In re Suboxone, 64 F. Supp. at 682-4. Therefore, as a general evidentiary matter, it makes sense that evidence which disproves these allegations is also relevant.

Judge Diamond recognized this point in Doryx. In granting summary judgment on the issue of exclusionary conduct, Judge Diamond found that the record established that the plaintiff "remains able to reach consumers through, *inter alia*, advertising, promotion, cost competition, or superior product development." Doryx, 2015 WL 1736957, at *14. Evidence which demonstrates the continued availability of these forms of competition is exactly the type of discovery that Indivior wishes to explore in the case before me.

As noted in my motion to dismiss ruling, "[t]he test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit. . . . As recognized in TriCor, "[c]ompetitors need not be barred 'from all means of distribution,' if they are barred 'from the cost-efficient ones.'" In re Suboxone, 64 F. Supp. at 683. Indivior

seeks the discovery at issue to explore whether the alleged "product hop" actually excluded Direct Purchasers from cost efficient means of competition or severely restricted the market. Indeed, the defendant in Doryx prevailed on summary judgment before Judge Diamond by relying on the very type of evidence sought by Indivior.

Moreover, Direct Purchasers' argument that Congress and the states have already determined that the automatic generic substitution system is the sole cost-efficient means of generic competition has no solid precedential support. The cases on which Direct Purchasers primarily rely – TriCor and Namenda II – do not stand for the proposition that it has been conclusively established that the automatic generic substitution system is the sole cost-efficient means of generic competition.

In TriCor, the court denied a motion to dismiss the plaintiffs' product hop claim. In doing so, the court noted that plaintiffs had alleged that they were prevented from availing themselves of the substitution system as a result of the defendants' alleged product hop and that the automatic generic substitution system was "alleged to be their cost-efficient means of competing in the pharmaceutical drug market." TriCor, 432 F. Supp. 2d at 423 (emphasis added). The court held that "[s]uch a restriction on competition, if proven, is sufficient to support an antitrust claim in this case." Id. (emphasis added). But TriCor did not hold that the automatic general substitution system is the only cost-efficient means of generic competition as a matter of fact or law. Rather, the court found that plaintiffs had plausibly alleged that the generic substitution system was their cost-efficient means of competition.

Similarly, I am not persuade by Direct Purchasers' argument that the import of the Second Circuit's holding in Namenda II is that the automatic generic substitution system is the only cost-efficient means of generic competition. Namenda II is also factually and procedurally

distinguishable. In that case, shortly before the patent was set to expire on defendant's Alzheimer's drug, Namenda IR, defendants launched a new version, Namenda XR. The Second Circuit affirmed the district court's grant of a preliminary injunction requiring the defendants to continue marketing Namenda IR until after the patent expired. The Second Circuit reviewed the district court's findings of fact and held that the issuance of the preliminary injunction was not an abuse of discretion. 787 F.3d at 643. In doing so, the Second Circuit noted that, the district court found that (1) the defendant's conduct was "coercive" because it "forced patients to switch from Namenda IR to XR"— the only other memantine drug on the market" and (2) "competition through state drug substitution laws is the only cost-efficient means of competing available to generic manufacturers." Id. at 647, 654, 655-656.

While the district court's findings in Namenda II align with Direct Purchasers' arguments, I agree with Indivior that the district court viewed the foreclosure of competition as a question of fact, concluding that the plaintiffs had adequately demonstrated both coercion and foreclosure in light of an established record which included the testimony from twenty-four witnesses and over fourteen hundred exhibits. However, in the case before me that record has not been developed and Indivior should be given that opportunity.

In sum, Namenda II and TriCor did not hold, as a matter of law, that in every pharmaceutical antitrust case, the automatic generic substitution system is the only cost-efficient means of generic competition. What is still at issue is whether the practices in question severely restricted the market. In order to establish antitrust liability, plaintiffs must prove antitrust injury, which is to say "injury of the type the antitrust laws were intended to prevent and that flows from the which makes defendants' acts unlawful." Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977). This injury must include consideration of whether Defendant's conduct

severely restricted the market. Dentsply In'l Inc., 399 F.3d at 191. To the extent that discoverable evidence is available regarding Direct Purchasers' ability to compete in the market despite the alleged "product scheme," Indivior is entitled to explore that discovery.

At this stage of the case, I am not prepared to conclude that downstream data is irrelevant to issues of liability in the product hop context. That said, the analysis that Dr. Normann proposes may not be feasible or, alternatively, may not support Indivior's contention that Direct Purchasers were able to efficiently compete outside of the automatic generic substitution system. But, without the benefit of a fully developed record, rulings regarding the market dynamics in this context would be premature and speculative.

c. Proportionality

Indivior additionally contends that Judge Rice erred in applying Rule 26(b)(1)'s proportionality requirement because he erroneously placed no value on the discovery sought. Noting that Direct Purchasers have already committed to producing all data regarding their purchases of Suboxone and its generic equivalents, Indivior claims that there is no incremental burden from Direct Purchasers producing sales data "of the exact same products." (Def.'s Objs. p. 20.)

Direct Purchasers assert that Judge Rice properly concluded that the marginal probative value of this evidence is outweighed by the costs and burden imposed on Direct Purchasers. According to Direct Purchasers, this conclusion was based on declarations provided by employees of Direct Purchasers and Indivior did not offer evidence to rebut this testimony.

As I detailed above, the probative value of the sought after discovery is potentially substantial because it may be relevant to factual issues at the heart of Direct Purchasers' antitrust theory of liability. I have reviewed the declarations Direct Purchasers submitted regarding the

cost and burden associated with producing this information and conclude that the cost considerations do not outweigh the probative value of production. Therefore, Indivior will be permitted to pursue discovery of downstream data.

IV. CONCLUSION

For the reasons recited above, I conclude that downstream data may be relevant to Direct Purchasers' product hop claim and that Indivior's request satisfies the Rule 26(b)(1) proportionality standard.